The Good, the Bad and the Ugly of bone-anchored prostheses: guideline to assess true clinical outcomes

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Frossard L. The Good, the Bad and the Ugly of bone-anchored prostheses: guideline to assess true clinical outcomes. First World Congress on Innovations in Amputation Surgery and Prosthetic Technologies. May 12-13, 2016, Chicago, Ill. USA. p 2

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Adj/Prof Laurent Frossard is a Biomechanist focusing on the locomotion and rehabilitation of individuals with lower limb loss. He is one of the very few independent experts in the clinical benefits of bone-anchored prostheses. His academic track record includes over 130 publications, several grants, supervisions of students and international collaborations.

Abstract
The aim of this study is to share the key elements of an evaluation framework to determine the true clinical outcomes of bone-anchored prostheses. Scientists, clinicians and policy makers are encouraged to implement their own evaluations relying on the proposed framework using a single database to facilitate reflective practice and, eventually, robust prospective studies.

Introduction
Bone-anchored prostheses are increasingly acknowledged as a viable alternative method of attachment of artificial limb compared to socket-suspended prostheses. To date, a few osseointegration fixations are commercially available. Several devices are at different stages of development particularly in Europe and the US. Clearly, the current momentum experienced worldwide is creating a need for a guideline to evaluate the true clinical outcomes of these procedures. The aim of this study is to share the key elements of an evaluation framework recently developed in Australia to determine the benefits and harms of bone-anchored prostheses.

Methods
The proposed evaluation framework to determine the true clinical outcomes bone-anchored prostheses for individuals with limb loss was built upon scoping review of the literature including seminal studies focusing on clinical benefits and safety of procedures involving screw-type implants and press-fit fixations. [1-64]

Results
As described in Figure 1, the literature review highlighted that a standard and replicable evaluation framework should focus on at least, but not limited to:

- The clinical benefits with a systematic recording of health-related quality of life (e.g., SF-26, Q-TFA), mobility predictor (e.g., AMPRO), ambulation abilities (e.g., TUG, 6MWT), walking abilities (e.g., characteristic spatio-temporal) and actual activity level at

baseline and follow-up post Stage 2 surgery (Figure 2),

- The potential harms with systematic recording of residuum care, infection, implant stability, implant integrity, injuries (e.g., falls) after Stage 1 surgery and up to two years follow-up (Figure 3).

Figure 1: Overview of an evaluation framework featuring a single database called Clinical Outcomes Registry to record, analyse and report benefits and harms following implantation of osseointegrated fixation for bone-anchored prostheses.

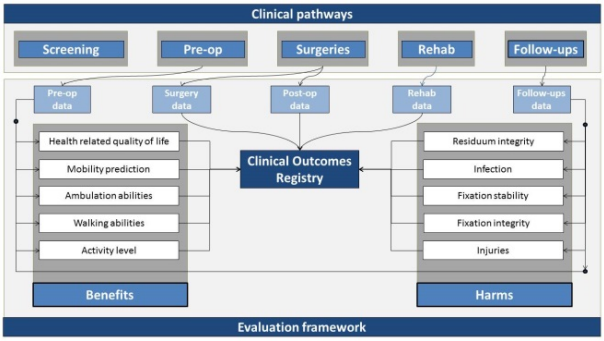


Figure 2: Assessments, domains, tools and variables to be considered for assessing benefits.

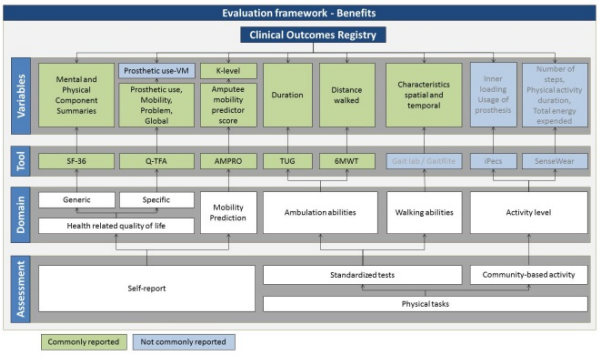
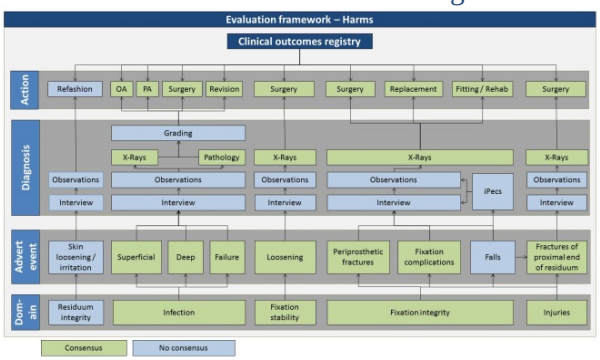


Figure 3: Assessments, domains, tools and variables to be considered for assessing harms.



Discussion

There was a general consensus around the instruments to monitor most of the benefits and harms. The benefits could be assessed using a wide spectrum of complementary assessments ranging from subjective patient self-reporting to objective measurements of physical activity. However, this latter was assessed using a broad range of measurements (e.g., pedometer, load cell, energy consumption). More importantly, the lack of consistent grading of infections was sufficiently noticeable to impede cross-fixation comparisons. Clearly, a more standardized grading system is needed.
Interestingly, there was little information on the technical platform that could be used to record, analyse and report this information (e.g., commercial software, web-based software) in a comprehensive manner fulfilling both best clinical and scientific practices (e.g., use of Google Form).

Conclusion

Scientists, clinicians and policy makers responsible for investigating the true clinical outcomes of bone-anchored prostheses using screw-type or press-fit osseointegrated implants are encouraged to implement their own evaluations relying on the framework featuring the domains and instruments suggested above using a single database to facilitate reflective practice and, eventually, robust prospective studies.

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